IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. EXELA PHARMA SCIENCES, LLC, Defendant.	Civil Action No. 22-1233-GBW

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MEMORANDUM OPINION

August 13, 2025
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is Exela's *Daubert* Motion to Exclude Dr. Emamifar's Opinions on Obviousness and Anticipation ("Motion" or "*Daubert* Motion") (D.I. 205), which has been fully briefed (D.I. 206; D.I. 232; D.I. 254).[1] For the following reasons, the Court denies Exela's *Daubert* Motion (D.I. 205). Exela's Request for Oral Argument (D.I. 262) is denied-as-moot.

I. BACKGROUND

This patent-infringement action concerns U.S. Patent Nos. 11,464,752 ("the '752 patent"), 11,426,369 ("the '369 patent"), and 11,571,398 ("the '398 patent") (together, the "Asserted Patents"). *See* D.I. 200 at 1. The Asserted Patents generally relate to 5 mg/mL ephedrine sulfate products. On February 28, 2025, Exela filed the present *Daubert* Motion. D.I. 205.

II. LEGAL STANDARD

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the U.S. Supreme Court held that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. 579, 597 (1993). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Third Circuit has explained:

[1] The Plaintiff is Nexus Pharmaceuticals, Inc. ("Nexus" or "Plaintiff"). The Defendant is Exela Pharma Sciences, LLC ("Exela" or "Defendant"). The Court also notes that this is the second of Exela's *Daubert* motions.

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have . . . [held] that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony . . . must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (cleaned up); *Kuhar v. Petzl Co.*, No. 19-cv-3900, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) (acknowledging the same trilogy).

Rule 702 "has a liberal policy of admissibility," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted); *see also United States v. Scripps*, 599 F. App'x 443, 447 (3d Cir. 2015) (same), as "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court," *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

III. DISCUSSION

Exela "requests that the Court exclude" the opinions from Nexus' expert, Dr. Amir Emamifar ("Dr. Emamifar"), that pertain "to the ultimate question of the obviousness and anticipation of the asserted claims." D.I. 206 at 17.[2] Exela offers two grounds in support of its request. The Court will examine the two grounds in turn.

[2] The precise scope of that which Exela seeks to exclude is not clear. In addition to requesting the Court to exclude Dr. Emamifar's "ultimate" opinions, Exela appears to request the Court to

With respect to Exela's first purported ground for exclusion, Exela contends that "Dr. Emamifar undertakes no comparison between any limitation of the asserted claims and the prior art" and, therefore, flouts 35 U.S.C. §§ 102-103, which require "consideration of the specific limitations of the asserted claims as compared to the prior art." D.I. 206 at 16. Exela cites several cases purportedly in support. *See* D.I. 206 at 17 (citing, e.g., *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 435-39 (D. Del. 2004) (excluding portions of expert's opinion on the issues of anticipation and obviousness where expert did not "perform an element-by-element comparison of each claim to each prior art reference")).

Exela's first purported ground for exclusion, however, is unavailing for at least three reasons. *First*, having reviewed the Rebuttal Expert Report of Amir Emamifar, Pharm.D., MBA Regarding Validity of U.S. Patent Nos. 11,426,369; 11,464,752; 11,571,398 ("Rebuttal Report") (D.I. 208-9, Ex. 9), the Court agrees with Nexus that Dr. Emamifar provides "specific and descriptive opinions that," at least purport to, "show non-obviousness and no anticipation" (*see* D.I. 232 at 13) that will be helpful to the finder of fact. With respect to anticipation, for example, Dr. Emamifar opines that "the stability and sterility for any compounded product cannot be inherent, because these features are not necessarily present even with the short BUD periods as shown by the consistent shortcomings that I listed above." D.I. 208-9, Ex. 9 ¶ 104. With respect to obviousness, Dr. Emamifar similarly opines that, "if Exela's experts did not show that any

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"exclude Dr. Emamifar from" offering any opinion or testimony "that the asserted claims are not obvious or anticipated." *See* D.I. 206 at 17. This difference in scope, however, is non-dispositive since the outcome of Exela's *Daubert* Motion is the same either way. In addition, even though Exela does not contend that Dr. Emamifar cannot issue ultimate opinions because Dr. Emamifar is an expert and not an attorney, the Court notes that "legal conclusions that a claim is" not invalid "are routinely given [by experts] in patent cases because they can be helpful to the jury." *See MHL Custom, Inc. v. Waydoo USA, Inc.*, No. CV 21-0091-RGA, D.I. 155 at 2 (D. Del. Feb. 3, 2023).

reference met the stability or sterility criteria as claimed, they could not have shown that the invention would have been achievable much less obvious." D.I. 208-9, Ex. 9 ¶ 114.

Dr. Emamifar supports these opinions with experiences and knowledge from his pharmaceutical practice. *See, e.g.*, D.I. 208-9, Ex. 9 ¶ 105 (opining that "it is not good pharmaceutical practice to assume that if a compounded product has a BUD of 90 days, that means it would meet a full set of FDA-related stability and sterility criteria for 12 months, including the claimed criteria" and that a "pharmacist could lose their license for providing a product that was used even one day after BUD except in the most dire circumstances, and holding that product for 12 months and assuming it could still be used and has the same features as at 90 days is not appropriate or justified").

Second, it is ironic that Exela contends that Dr. Emamifar's Rebuttal Report does not compare each limitation of the asserted claims with each element of the prior art references since Dr. Emamifar contends, for example, that it was Dr. Myers (Exela's expert), i.e., the expert of the party with the burden of demonstrating invalidity, who failed to "conduct any analysis on a product-by-product basis." D.I. 208-9, Ex. 9 ¶ 107. Indeed, a valid theory of invalidity requires, in the first instance, a claim-by-claim and element-by-element examination from the party with the burden of showing invalidity. *See Oxford Gene*, 345 F. Supp. 2d 431, 436 ("The second step in evaluating the validity of a patent is to perform an element-by-element comparison of each claim to each prior reference. . . . In opining that the '270 patent is invalid, [the expert from the party with the burden of demonstrating invalidity] should have followed [this] approach.").

Third, the cases from the Federal Circuit and this Court that Exela cites to contend that an expert report must include a claim-by-claim and element-by-element analysis (*see* D.I. 206 at 16-17) uniformly regard reports, not from the rebuttal expert, but from the expert of the party with the

relevant burden. *See, e.g.*, *Oxford Gene*, 345 F. Supp. 2d 431, 435-36 (regarding a report from an expert opining that the claimed invention was anticipated and obvious); *Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1373-74 (Fed. Cir. 2008) (regarding a report from an expert opining that the claimed invention was obvious); *Align Tech., Inc. v. 3Shape A/S*, No. 17-1646-LPS, 2020 WL 4926164, at *9-10 (D. Del. Aug. 14, 2020) (regarding a report from an expert opining that the claimed invention was anticipated and obvious). These cases are distinguished from the present action in that Dr. Emamifar issued and served a *rebuttal* report opining *inter alia* that it was, in fact, Exela's expert that failed to perform the required analysis.

In summary, given the circumstances of this case described above, that Dr. Emamifar purportedly did not perform a claim-by-claim and element-by-element analysis is not a sufficient basis for the "extreme sanction" of excluding his opinion and testimony from trial with respect to the question of obviousness and anticipation. *See Inline Connection Corp. v. AOL Time Warner Inc.*, 470 F. Supp. 2d 435, 441 (D. Del. 2007).

With respect to Exela's second purported ground for exclusion, Exela contends that "Dr. Emamifar merely restates that Dr. Fix will opine on validity" and that such "regurgitation of Dr. Fix's opinions 'adds nothing and therefore is not helpful to a jury.'" D.I. 206 at 17 (citing *XpertUniverse, Inc. v. Cisco Sys., Inc.*, C.A. No. 09-157-RGA, 2013 WL 865974, at *3 (D. Del. Mar. 7, 2013)). However, as shown above, Dr. Emamifar does more than "merely restate" that "Dr. Fix will opine on validity." *See* D.I. 208-9, Ex. 9 ¶¶ 104, 114; *see also id.* ¶ 105 (opining, for example, that a "pharmacist could lose their license for providing a product that was used even one day after BUD except in the most dire circumstances, and holding that product for 12 months and assuming it could still be used and has the same features as at 90 days is not appropriate or justified").

In addition, that Dr. Emamifar acknowledges that Dr. Fix also opines on invalidity (*see, e.g.*, D.I. 208-9, Ex. 9 ¶ 102 ("Dr. Myers asserts that several of the Asserted Claims are invalid as anticipated by the prior art. For the reasons described below, I disagree. Further, I understand that another expert, Dr. Fix, will provide additional opinions in response to Dr. Myers's anticipation analysis.")) does not justify the extreme sanction of excluding Dr. Emamifar's opinion and testimony on the question, ultimate or otherwise, of the purported "obviousness and anticipation of the asserted claims" (*see* D.I. 206 at 17).

IV. CONCLUSION

For all the foregoing reasons, Exela's *Daubert* Motion to Exclude Dr. Emamifar's Opinions on Obviousness and Anticipation (D.I. 205) is DENIED. Also, Exela's Request for Oral Argument (D.I. 262) is DENIED-AS-MOOT.